

## VAMHCS RESEARCH SERVICE HOT TOPIC

Vol. 4 No. 1  
March 15, 2010

### Revised Templates for VAMHCS Informed Consent Form (ICF) and HIPAA Authorization

***A REVISED ICF TEMPLATE FOR VAMHCS STUDIES AND A REVISED HIPAA AUTHORIZATION HAVE BEEN POSTED ON THE HRPO WEBSITE.***

***Effective immediately, the revised templates must be used for all new protocols and renewing protocols, and must be included when you submit modifications for other reasons. YOU DO NOT NEED TO HOLD UP ANY RESEARCH ACTIVITIES IN THE MEANTIME.***

- ▣ Are you tired of having your R&D Committee approval delayed because your VAMHCS informed consent form (ICF) did not meet VA- or VAMHCS-specific requirements? Too many injury statements to juggle? Confused as to which “destruction of data” statement to use this month?

Well, take a breath. Relief is here!

- ▣ A revised VAMHCS ICF template and a revised HIPAA authorization template have been posted on the HRPO website.
- ▣ The tutorial below gives details on the changes. Please use the versions attached to this Hot Topic to follow the tutorial.
- ▣ For any **new protocols**, any **renewals**, or when you **modify** your protocols for other reasons, ***please use the new versions of the ICF and HIPAA authorization*** for the new, renewing or modified protocol!
- ▣ **You do not need to stop any research activities in the interim.**

■ **YOU DO NOT NEED TO RECONSENT OR 'RE-HIPAA' CURRENT PARTICIPANTS UNLESS THE IRB REQUIRES YOU TO DO SO.**

■ Revisions to the VAMHCS informed consent template and other important items:

- **Refer to the attachment: “Tutorial REVISED VA ICF template...” to guide you through the items below.**
- The content on pages 1-4 (Required elements of informed consent): MUST be identical between the VAMHCS ICF and the UM ICF.
- Page 3, “Alternatives” section: The VAMHCS is included in the “*This is not a treatment study...*” statement.
- Page 4, “Confidentiality” section:
  - A new, required statement that the VHA may inspect research records;
  - A new, required statement stating where records will be kept: simply state the institution where records will be kept (UMB, UMMS, VAMHCS, UMBC, etc.). This fulfills requirements for the VA Information Security Office and the VA Privacy Office. Do not use room numbers or other specifics (otherwise you would need to amend the ICF every time you moved spaces).
  - New language REQUIRED by VA Office of Oversight (ORO):  
“Your research records and/or identifiers will be retained in accordance with the VA records control schedule.”  
This is the latest and hopefully final ‘destruction of data’ language requirement. It is followed by a short explanation for research staff and participants about the ‘records control schedule’. Remember that for now, you cannot destroy any research-related records. Whenever a records control schedule for VHA research records is issued, there will be rules for retention or destruction of records that will need to be followed at that time.
- Page 4-5, several points where VA contact information is required: please include the specific phone extension. The VAMHCS main phone number, 410-605-7000, puts participants in contact with VAMHCS operators who may not be able to connect them to appropriate research staff.

- If your extension begins with a “7”, then the participant would be able to dial directly to your office. For example, the extension for the Research Service is “7130” and the Research Service office can be reached directly by dialing 410-605-7130.
- However, extensions beginning with digits other than “7” do not work. For example, the extension for the Office of Research Compliance is “6512”. Dialing 410-605-6512 will not connect to a working number.
- Page 5: There is a new statement that the VAMHCS has designated the UMB IRB to review the research study. This will hopefully explain to a VAMHCS patient why there is a University of Maryland statement on their consent form.
- Page 5, “Minimal Risk” University statement: The VA injury statement is included.
- Page 6: The VAMHCS Office of Research Compliance contact information is now provided. There is also a statement to participants that the ORC *may* contact them in the future. This would be done by the ORC as a quality assurance/participant outreach activity to assess participant satisfaction or suggestions.
- Page 6, “Greater Than Minimal Risk” University statement: The conflicting University injury statement has been removed and the VA injury statement inserted.
- Page 7: The same VAMHCS Office of Research Compliance statement as above has been added.
- Page 8: Guidance to investigators that children cannot be research participants for a VA study unless a waiver from VA Central Office (Chief Research & Development Officer, “CRADO”) has been obtained.

■ Revision to the HIPAA authorization

- Note that the footer now identifies the authorization as “Version: 03.01.2010”.
- The “destruction of data” clause has been removed completely.

■ The revised templates are available on the HRPO website through the “CICERO” page or the “Investigator Toolkit” page, and will also be posted on the CICERO site, accessible from within your protocol applications.

- FINAL TIP: In CICERO, when choosing your approved informed consent form to use with a participant, **BE SURE TO CHOOSE THE “WITH LOGO” VERSION of the approved ICF!!!!**
- If you choose the “Without Logo” version, YOU WILL HAVE AN INVALID ICF!!! The “without logo” version does not contain the validation footer for IRB approval.
  - **Erroneous use of the “without logo” version of the ICF has led to numerous instances of noncompliance.**
  - The purpose of the “without logo” version is for investigator convenience. In BRAAN, investigators did not have access to Word versions of their ICFs to use when they wanted to modify the ICFs. If they had not saved their own Word versions, they needed to write from scratch every time they needed a changed/new ICF. The HRPO responded to investigator feedback by building in this feature into CICERO. However, an unintended consequence is that the incorrect (invalid) version of the ICF has been used for consent of participants.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

Jessica Mendoza,  
Acting Research Compliance Officer  
Room 3A-125  
410-605-7000 x6512  
[jessica.mendoza@va.gov](mailto:jessica.mendoza@va.gov)

Can't put your finger on a past Hot Topic you know would solve your problem? No problem. Check the Hot Topics archive on the Research Service website:

[http://www.maryland.research.va.gov/hot\\_topics.asp](http://www.maryland.research.va.gov/hot_topics.asp)

For comments, complaints or suggestions regarding the Research Service or Office of Research Compliance, contact:

Jessica Mendoza,  
Acting Research Compliance Officer  
Room 3A-125  
410-605-7000 x6512  
[jessica.mendoza@va.gov](mailto:jessica.mendoza@va.gov)